

WHO Immunisation Devices - Performance, Quality & Safety

E006: Temperature monitoring devices





HEATmarker® VVM1 Product name:

IMD-PQS Code: F006-071 Status: Prequalified 01 Nov 2021 Date of acceptance: E006

Appliance type:

Product description: Vaccine Vial Monitor Type 1

Temptime Corporation, A Zebra Technologies Company Manufacturer:

Manufacturers Reference: HEATmarker® VVM1 Country of Manufacture: United States of America

Address: 116 American Road, Morris Plains, NJ, 07950, United

States

United States of America

+1 973 630 6000 Telephone: Email: rorie.doty@zebra.com

Website address: www.zebra.com/tempmonitoring

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Mode of operation Chemical **Activation mechanism** Always active

Fixing mechanism Adhesive **CE** marking Yes Time to endpoint at 37°C 1.00 Time to endpoint at 5°C (days) 100.00

(days)

MECHANICAL AND ELECTRONIC DEVICES ONLY

Power source Passive device Alarm type NA

Memory size (Mb) 32.0000000000 Display medium Color change

Recording medium Not applicable

Comments Full labels (typically white or clear liner) and dots (typically brown or clear liner) are made on

> lightweight litho/paper/film facestock offering exceptional printability and flexibility. The service temperature range for the adhesive is typically -40°F to 160°F, or wider. Liner (can either be PET or coated paper) is designed for label dispensing applications. A clear film-based over-laminate is used for dots (brown liner) for added stability and protection. Custom solutions including a combination of approved litho/paper/film substrate and over-laminate (if applicable) are available

upon request

PRICE AND SHIPPING

EXW Minimum order 500000.00 Incoterms Price 1 On request to manufacturer Year of base price 2021

QUALITY STANDARD

Quality Standard ISO 13485;Other **Quality standard (Other)** ISO 9001:2015

Specification Reference Applicable PQS specification: E006/IN05.4 Applicable PQS

VP(s): E006/IN05-VP.4

VERIFICATION

Verification Laboratory 0013X00004MI8OIQAJ Verification Report Reference LLTPL/2021/06-01

PRODUCT SITES

Organization name Temptime Corporation, A Zebra Technologies Company

Address 116 American Road, Morris Plains, NJ, 07950, United States

United States of America

Current PQS status: Prequalified Valid until: 31 May 2026

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.